DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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WARNING LETTER

NWE-13-06W

April 25 2006

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert W. Schaefer, President/Owner
Apple Medical Company
28 Lord Road
Suite 135
Marlborough, Massachusetts 01752

Dear Mr. Schaefer:

During an inspection of your establishment located in Marlborough, Massachusetts, on November 14 – December 1, 2005, our Investigators determined that your firm manufactures gynecologic electrocautery devices. As such, the Fischer Cone Biopsy Excisors (FCBE) are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to complete and implement complaint handling procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a). For example, 62 complaints were reviewed since March 2002. Your firm's "Processing of Product Complaints and Credit Returns Procedure" (GP-019, revision D, released May 9, 2002) states in section 6.0 7.0 and 7.12:

A. [redacted]

However, [redacted] of 62 complaints had no justification in the file stating why no investigation took place. This includes complaints numbered [redacted].

B. [redacted]

However, [redacted] 62 complaints were missing this information. This includes complaints numbered [redacted]

C. [redacted]

However, [redacted] of 62 complaints were missing this form. This includes complaints numbered [redacted]

D. [redacted]

However, [redacted] of 62 complaints were missing this information. This includes complaints numbered [redacted]

E. [redacted]

However, [redacted] of the entire group of 62 complaints were missing this information according to the product complaint log.

We are in receipt of correspondence from Mr. John C. Pulford, Director of Operations, Management Representative, dated December 19, 2005, submitted in response to the FDA 483 issued to your firm at the end of the recent inspection on December 1, 2005. We have reviewed your responses.

The response to item A (FDA 483 observation 3 A.) states a list of all complaint files that were reviewed and returned to a "complete" status by Apple personnel were provided to the FDA investigator. The files were associated with complaints numbered 80 to 105. Your response is not adequate because complaints numbered [redacted] were missing the name of the individual responsible for making the investigation decision and date of the complaint.

The response for item B (FDA 483 observation 3 B.) states a list of all complaint files that were reviewed and returned to a "complete" status by Apple personnel were provided to the FDA investigator. The files were associated with complaints numbered 80 to 105. Your response is not adequate because complaints numbered [redacted] were missing a reply to complainant.

The response for items C and E (FDA 483 observations 3 C. and E.) appear to be adequate in that you provided documentation to show all complaint files (Product Complaint Log) have been reviewed to ensure they are closed in a timely manner and any missing forms including the Telephone RGA Form (FM-03044) and/or required documents has been restored or generated where necessary. The adequate implementation of the corrective action will be verified during the next inspection.

The response for item D (FDA 483 observation 3 D.) states a list of all complaint files that were reviewed and returned to a "complete" status by Apple personnel were provided to the FDA investigator. The files were associated with complaints numbered 80 to 105. Your response is not adequate because complaints numbered [redacted] were missing the catalog number and a description of the incident.

2. Failure to ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under the Medical Device Reporting (MDR) regulation, as required by 21 CFR 820.198(a)(3). For example, your complaint and MDR process is flawed, as described below.

   Your MDR decision tree prevents the detection and forwarding of events that should be reviewed for an MDR determination. The "opening" conditional statement in your MDR decision tree states, [redacted] does not meet the reporting standard in the MDR regulation. The requirement in 21 CFR 803.50 states that a device, "May have caused or contributed to a death or serious injury. . . ." Your use of the word "has" limits the complaints or information to situations where there is an established cause and effect relationship rather than a possible cause and effect relationship, as required by the MDR regulations. The MDR decision tree also gives the impression that the MDR reporting decision is made solely upon information received by the firm in that you state, [redacted] MDR requires that manufacturers determine if a complaint is an MDR reportable event based upon its investigation and evaluation of the cause of the event. Additionally, the melting of the FCBE should, at a minimum, be reported as a malfunction since this type of malfunction would be likely to cause or contribute to serious injury if it were to recur.

   Mr. Pulford's response to this observation (FDA 483 observation 4 b) is not adequate because your decision tree continues to use language that prevents the detection and forwarding of events that should be reviewed for an MDR determination.

   Mr. Pulford's response to FDA 483 observation 4 a. appears to be adequate. In your response, you provided the MDR Decision Tree forms for complaints numbered 46, 49 – 52, 54 – 61, 63, 68, 70 - 72, 75, 77, 78, 80, 87, 88, 92, 94, 101 and 103 – 105.

3. Failure to perform risk analysis, as required by 21 CFR 820.30(g). For example, two Engineering Change Orders (ECOs) (#106 and #120) regarding [redacted] on the FCBE were identified during the review of your firm's Device Master Record. ECO# 106 describes a [redacted], implemented January 17, 2002. No risk analysis was completed using your Risk Analysis

Procedure nor was a completed risk analysis located in the Device Master Record. ECO# 120 describes a [redacted] because of customer complaints related to the failure of the FCBE. The ECO# 120 was implemented December 18, 2003. Likewise, no risk analysis was documented for this change.

Mr. Pulford's response to this observation (FDA 483 observation 2) is not adequate because none of the documentation submitted by your firm provides evidence of a corrective action or proposed preventive action for lack of performing a risk analysis. The response states that a risk analysis would be generated under the scope of a design change that could significantly affect the safety and effectiveness of the FCBE, and it would be included in a new 510(k), traditional or special. However, the response indicates that your firm believes that a new 510(k) is not required for the FCBE material change based on guidance derived from the FDA Guidance Document "510(k) Memorandum #K97-1, Deciding When to Submit a 510(k) for a Change to an Existing Device, dated January 10, 1997". You also believe that the FCBE device modifications were properly implemented without conducting a formal risk analysis.

However, the [redacted] was made based upon known safety and effectiveness issues associated with a product complaint in 2003 related to the melting of the device's electrodes (Product Complaint 58 & RGA# R193). Your Risk Analysis Procedure (GPP-048, revision A, approved May 3, 1999) states under section 1.0 that risk analysis is designed to provide a formal, documented means of reviewing the safety of Apple Medical Corporation devices by identifying the hazards and estimating the risks associated with the device. No risk analysis was performed to determine [redacted] change for the FCBE would prevent the burning and/or melting of the device's electrodes or create new potential hazards. The [redacted] change for the FCBE was implemented in December 18, 2003 and your firm continued to receive product customer complaints for 2004 and 2005 related to the burning and/or melting of the devices (complaints numbered 72, 87, 88, 92, 94 and 104).

4. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). For example, the day to day operations as related to your CAPA program do not follow your written CAPA procedure (GP-039). You do not use the Corrective Action Request (CAR)

forms or CAR logs as stated in the procedure and complete the CAPA requirements through ECOs and complaint files. Additionally, your complaint files were incomplete and the CAR response requirements are not being met.

Mr. Pulford's response to this observation (FDA 483 observation 7) is not adequate in that you need to submit the revised Corrective Action procedure (GP-039) to this office for final review. The response states the procedure will be implemented prior to January 31, 2006. The response also agreed with the investigator's conclusion for the CAR response requirements not being met and stated the corrective actions will be identified, logged and controlled within a single element of the quality system.

5. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your firm failed to perform audits in 2004 and 2005.

   Your firm's Quality System Audit Procedure (GP-042, revision C, released May 6, 2002) [redacted]

   The Quality Assurance Program Requirements Procedure (QAPR-001, revision B, issued May 3, 1999) states on page 43, under section 17.2 that a complete internal quality audit shall be completed [redacted]

   Mr. Pulford's response to this observation (FDA 483 observation 5) is not adequate because the documentation you submitted failed to include evidence of internal audits that were performed in 2004 and 2005.

6. Failure to promptly remove obsolete documents from all points of use, as required by 21 CFR 820.40(a). For example, your firm's quality manual titled, "Quality Assurance Program Requirements" (QAPR-001, revision B, issued May 3, 1999) shows obsolete documents, such as a distribution list on page 3, issued May 3, 1999, showing 6 personnel, 3 of whom are no longer with the firm, an outdated table of contents, and an outdated organizational chart.

Mr. Pulford's response to this observation (FDA 483 observation 6) is inadequate because your firm failed to submit your updated quality manual, including revised pages showing that the appropriate changes have been made.

This inspection also determined that significant changes were made to the design of the FCBE devices, and in particular [redacted] of the devices, that could significantly affect the safety or effectiveness of the device. The FCBE devices are misbranded under section 502 (o), 21 U.S.C. 352(o), in that a notice or other information respecting the modification to these devices was not provided to the FDA as required by section 510(k), 21 U.S.C. 360(k), and 21 CFR 807.81(a)(3)(i).

The FCBE devices with the [redacted] are adulterated under section 501(f)(1)(B), 21 U.S.C. 351(f)(1)(B), in that the they are class III devices under section 513(f), 21 U.S.C. 360c(f), and do not have an approved application for premarket approval in effect pursuant to section 515(a), 21 U.S.C. 360e(a) or an approved application for an investigational device exemption under section 520(g), 21 U.S.C. 360j(g). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b).

Additionally, the above-stated inspection revealed that the FCBE devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C 352(t)(2), in that your firm failed or refused to furnish any material or information required by or under section 519 of the Act, 21 U.S.C. 360i, respecting the device and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation and 21 CFR Part 806 - Correction and Removals regulation.

1. Significant MDR regulation violations include, but are not limited to, the following:

   A. Failure to develop, maintain, and implement written MDR procedures for internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 CFR 803.17(a)(1). For example, your firm's written MDR procedure (US Medical Device Reporting and EU Vigilance -Document Control Procedure - GP-020 - revision C – approved May 3, 1999), page 3 of 5, item 5.6.1, includes labeling questions (frequency and severity) that reflect the 1984 version of MDR and; therefore, is not in compliance with the current MDR reporting requirements. The labeling language

used in the decision tree was removed from the 1984 version of the MDR regulation during subsequent revisions. The current rule was published on Monday, February 28, 2005, and became effective on July 13, 2005.

The logic of your firm's written procedures in 5.6.1 is not valid and would result in erroneous conclusions regarding a decision to submit/not submit an MDR. Therefore, section 5.6.1 of the procedure does not provide for the timely and effective identification, communication, and evaluation of events that may be subject to the MDR requirements.

B. Failure to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example, you did not submit an MDR report to the FDA for an adverse event (MW1030679 – Dated December 29, 2003) that required medical intervention for the removal of the broken piece of the device in the patient's endocervical canal. You should have submitted an MDR report for this adverse event. Additionally, your written MDR procedure (US Medical Device Reporting and EU Vigilance -Document Control Procedure - GP-020 - revision C – approved May 3, 1999) [redacted]. This is an incorrect interpretation of the MDR regulation.

Your decision tree, [redacted] regarding the reporting of a device malfunction. Remedial action is addressed in 21 CFR 803.53 - Five-day MDR reports. A "Remedial action means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event." Therefore, if you receive a malfunction report and initiate a remedial action to prevent an unreasonable risk to the public health, the malfunction is reportable as an MDR five day report. However, if you do not initiate a remedial action, the malfunction is still subject to the reporting requirements in 803.50(a)(2). i.e. to determine if the event should be reported to FDA within 30 days. Therefore, your decision tree, [redacted] does not comply with the reporting requirements

of MDR and could result in the failure to submit a reportable MDR malfunction.

2. Significant Correction and Removals regulation violations include, but are not limited to, the following:

   Failure to submit a written report to FDA of any correction or removals of a device initiated by the manufacturer if the correction or removal was initiated to remedy a violation of the act caused by the device which may present a risk to health, as required by 21 CFR 806.10(a)(2). For example, your firm received complaints regarding various problems such as melting and burning associated with the insulation on the FCBE. The complaints were determined to meet the requirements for a Class II recall, however, you did not submit a written report of your correction.

   Mr. Pulford's response to this observation (FDA 483 observation 1) is inadequate in that even though none of your FCBE failures caused patient injuries or death, we have determined that the FCBE failures may present a risk to health because retention of metal from the melted FCBE has the potential for serious injury or death associated with perforation of body organs as well as postoperative hemorrhage.

   We note that this above corrective action only applies to the FCBE. However, it is your responsibility under the Quality System regulation to review all complaints. If complaints concerning your other devices reveal that corrective action is necessary you should contact the New England District Officer's recall coordinator, Susan Liner at 781-596-7750. We acknowledge that you are working with FDA in recalling the FCBE devices made before the manufacturing change took place in 2003. Your voluntary action in this Class II recall is noted and we look forward to working with you now and in the future. If you have any questions in this recall or any future recalls please call Susan Liner, Recall Coordinator at 781-596-7750.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket approval applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Bruce R. Ota, Compliance Officer, New England District Office, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. If you have any questions about the contents of this letter please contact Mr. Ota at (781) 596-7762.

Sincerely yours,

Gail T. Costello
District Director
New England District